

4-13-93

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
BEFORE THE ADMINISTRATOR

In the Matter of )  
 )  
Bio-Tek Industries, Inc., ) Docket No. FIFRA-92-H-06  
 )  
Respondent )

1993 APR 13 PM 2:26  
EPA/REG-1117

ORDER DENYING MOTION TO DISMISS  
BASED ON THRESHOLD LEGAL ISSUES

The complaint in this proceeding under section 14(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 1361(a)(1), issued on June 25, 1992, charged Respondent, Bio-Tek Industries, Inc. with 23 counts of submitting false compliance statements in connection with studies submitted to the Agency in support of an application for registration of a pesticide product, Tek-Phene Cleaner-Disinfectant-Deodorant. Specifically, it was alleged that in its application for registration of the mentioned pesticide, Bio-Tek submitted signed statements that studies, for which it was a sponsor as defined in 40 CFR § 160.3, submitted to the Agency on May 31, 1990, in support of the application were conducted in compliance with GLPS regulations, 40 CFR Part 160. These statements were allegedly false in various respects. For these alleged violations, it was proposed to assess Bio-Tek a penalty totaling \$100,000.

Bio-Tek answered, admitting that it was a registrant and a sponsor of the studies identified in the complaint, admitting that Microbac Laboratories, Inc. Southeast Division ("Microbac") was the

testing facility which conducted the studies at issue, but alleging that the only statement Bio-Tek signed was as follows: "(a) statement attesting to compliance with Good Laboratory Practice Standards, signed by the Study Director is found above." Bio-Tek alleged that it relied on the assurances of the testing laboratory and the signed statement of the study director that the studies were conducted in full compliance with GLPS. Accordingly, Bio-Tek denied submitting any false statements to EPA, denied violating any provision of FIFRA and requested a hearing. Bio-Tek also raised certain affirmative defenses including its inability to pay.

#### Bio-Tek's Motion To Dismiss

Bio-Tek submitted pre-hearing exchange information in accordance with a directive of the ALJ by letter, dated February 26, 1993. Included with the letter was a Motion To Dismiss Based On Threshold Legal Issues.

Bio-Tek stated that it is a small, family-owned business engaged in the manufacture of disinfectant products. Bio-Tek acknowledged submitting the two efficacy studies identified in the complaint, EPA No. MRID 41513411 (Lab. Report Nos. 34068-I and 34069-I) and No. MRID No. 41513410 (Lab. Report Nos. 34068-H and 34069-H) to the Agency on May 31, 1990, in support of its application for registration of its "Tek-Phene" Cleaner Disinfectant Product, EPA Registration No. 11725-8 (Motion at 2). Both of the mentioned studies were performed by Microbac Laboratories and both contained a certification signed by the study

director, Mr. Sam Spring, that "(t)his study was conducted in accordance with the Good Laboratory Practice Standards set forth in 40 CFR Part 160." Bio-Tek's compliance statement for each of the studies was signed by Ms. Joyce B. Pazianos, Pazianos Associates, Agent for Bio-Tek, and stated: "A statement attesting to compliance with Good Laboratory Practice Standards, signed by the Study Director, is found above."

According to Bio-Tek, it selected Microbac, because Microbac had a good reputation in the community, and had previously performed studies for Bio-Tek which had been accepted by EPA. Moreover, Bio-Tek states that its President, Ms. Cindy L. Simpukas, specifically informed Microbac, prior to initiation of the studies, that the studies were required to be conducted in accordance with GLPS and that Ms. Simpukas was assured by the laboratory director that the studies could and would be performed in accordance with GLPS (Motion at 3). Bio-Tek assertedly agreed to pay a higher price for the studies, because of the GLPS requirement.

Bio-Tek quotes FIFRA § 12(a)(2)(Q), which makes it unlawful to falsify, inter alia, all or part of any information relating to the testing of any pesticide, and points out that there is no reference to GLPS in FIFRA. Referring to the regulations (40 CFR Part 160) describing GLPS applicable to the performance of studies submitted in support of applications for pesticide registrations, Bio-Tek says that the regulations do not provide any guidance on the procedures the applicant must follow to monitor a laboratory's compliance with GLPS (Motion at 4). Moreover, Bio-Tek asserts that

the only obligation of the applicant is to inform the laboratory that the study must be performed in accordance with GLPS, citing 40 CFR § 160.10,<sup>1/</sup> and to include a GLPS "compliance statement" with the study, citing 40 CFR § 160.12.<sup>2/</sup> The latter section makes it clear that the applicant or sponsor and the study director must submit signed compliance statements. Bio-Tek states that in practice the Agency has routinely accepted "derivative statements," i.e., a statement by the registrant certifying that the study

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<sup>1/</sup> The cited regulation, 40 CFR § 160.10, provides:

When a sponsor or other person utilizes the services of a consulting laboratory, contractor, or grantee to perform all or a part of a study to which this part applies, it shall notify the consulting laboratory, contractor, or grantee that the service is, or is part of, a study that must be conducted in compliance with the provisions of this part.

<sup>2/</sup> Section 160.12 provides:

Any person who submits to EPA an application for a research or marketing permit and who, in connection with the application, submits data from a study to which this part applies shall include in the application a true and correct statement, signed by the applicant, the sponsor, and the study director, of one of the following types:

(a) A statement that the study was conducted in accordance with this part; or

(b) A statement describing in detail all differences between the practices used in the study and those required by this part; or

(c) A statement that the person was not a sponsor of the study, did not conduct the study, and does not know whether the study was conducted in accordance with this part.

director has attested that the study was conducted in accordance with GLPS.

Because the statement signed by Bio-Tek was literally accurate and because Bio-Tek did not make any representation that it had any knowledge beyond the statements of the study director that the studies were performed in accordance with GLPS, Bio-Tek argues that it did not make a false statement and cannot be charged with a violation of FIFRA § 12(a)(2)(Q) (Motion at 5, 6). Additionally, Bio-Tek contends that EPA's attempt to hold it responsible for acts of a laboratory over which it has no control exceeds the Agency's authority under the Act and violates Bio-Tek's due process rights. By attempting to turn Bio-Tek's compliance statement, which the Agency has accepted in satisfaction of the requirements of 40 CFR § 160.12 at the time of registration, into a false statement, Bio-Tek asserts that it is being held responsible for alleged acts of the laboratory not committed by Bio-Tek and of which Bio-Tek was unaware. It points out that prior attempts of the Agency to hold a regulated entity responsible for acts of another person over whom the regulated entity had insufficient control have been unsuccessful, citing, e.g., Amoco Oil Company v. EPA, 543 F.2d 270 (D.C. Cir. 1976) (Clean Air Act regulation imposing liability on refiner for sales of contaminated [leaded] gasoline by retailer, held invalid).

Bio-Tek also argues that, because the GLPS regulations fail to provide any notice to registrants of any specific duties to monitor the performance of the test laboratory, it may not be assessed a

penalty for the violations alleged herein (Motion at 10). It points out that the Agency has failed to state, even in general terms, the steps the registrant must take to [assure that the laboratory has complied with GLPS] and contends that in the absence of directives or guidance on the duty to monitor, it is a violation of due process to hold the registrant accountable for violations by the test laboratory unascertained by, or unknown to, the registrant (Motion at 11). Quoting Rollins Environmental Services v. EPA, 937 F.2d 649 (D.C. Cir. 1991), Bio-Tek asserts that it is a cardinal rule of administrative law that "a party cannot be found to have violated a regulatory provision absent 'fair warning' that the allegedly violative conduct was prohibited," dissenting and concurring opinion of J. Edwards.

Bio-Tek also contends that it may not be held accountable for the violations allegedly committed by Microbac, because it was not on notice that a derivative compliance statement is unacceptable, or that such a statement will subject registrants to enforcement action if the laboratory is found not to be in compliance (Motion at 15). By accepting studies containing derivative compliance statements, and issuing registrations based on such statements, Bio-Tek says that EPA signaled to registrants that such statements were acceptable despite the absence of direct certification as to the registrant's independent knowledge of the lab.'s compliance with GLPS. According to Bio-Tek, proper application of the policy of allowing the registrant to rely on the certification of the lab that a study was performed in accordance with GLPS, means that the

registrant would only be liable for the submission of a false statement, if he had knowledge at the time the compliance statement was signed or submitted that the study was not performed in accordance with GLPS (Motion at 16).

Additionally, Bio-Tek contends that EPA is barred from holding Bio-Tek responsible for any alleged violations of FIFRA, because the Agency accepted the compliance statement in satisfaction of 40 CFR § 160.12. Bio-Tek points out that section 160.12 (supra note 2) does not specifically delineate acceptable compliance statements, but merely gives broad categories of the types of statements, which will be found acceptable. It asserts that the Agency has confirmed that many types of statements can satisfy the requirements of section 160.12, citing PR Notice 86-5, July 29, 1986, at 9, 16.<sup>3/</sup>

Moreover, Bio-Tek alleges that, at EPA-sponsored data formatting workshops, Agency officials have sanctioned use of the type of sponsor statement submitted by Bio-Tek herein. Bio-Tek says because the Agency accepted Bio-Tek's compliance statements at the time of registration and did not require it to make any further

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<sup>3/</sup> PR Notice 86-5 provides in part at 9:

D.5 Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

Page 16 contains examples of blank GLP statements which, when completed, would comply with 40 CFR § 160.12.

certification regarding GLPS, EPA may not now hold Bio-Tek accountable for alleged violations of which it was unaware (Motion at 17, 18).

Although maintaining that, for reasons set forth above, this action should be dismissed, Bio-Tek contends that, because there were only two studies and two compliance statements, it may not be charged with more than two counts of submitting false statements (Motion at 18, et seq.). It says that decisions addressing the filing of false statements under federal law are clear that only a single count may be charged for each false statement, citing, e.g., U.S. v. Segall, 833 F.2d 144 (9th Cir. 1987) and U.S. v. Sahley, 526 F.2d 913 (5th Cir. 1976) (three false statements in a loan document for a single loan constituted a single transaction and a single violation for sentencing purposes).

Bio-Tek alleges that the administrative decisions are in accordance with the above rule, citing, e.g., In the Matter of Hawk Industries, Inc., I.F. & R. Docket No. II-120C (Initial Decision, December 21, 1976) (shipment of a pesticide misbranded in more than one way constituted a single offense for which only one penalty could be imposed).

#### Complainant's Opposition

On March 4, 1993, Complainant filed a reply to Bio-Tek's pre-hearing exchange and a motion in opposition to Bio-Tek's motion to dismiss (Opposition). Firstly, Complainant describes the importance of GLPS to the FIFRA registration and regulatory program

(Opposition at 2, 3). Secondly, Complainant argues that Bio-Tek did submit false compliance statements, pointing out that the statements were signed by the three parties identified in 40 CFR § 160.12, i.e., the study director, sponsor, and applicant. Complainant says that if Bio-Tek did not wish to represent that Microbac conducted the study in accordance with GLPS, it should have declined to sign the statement. As an example of why the statement was false, Complainant points to Bio-Tek's (Microbac's) failure to have a Quality Assurance Unit as mandated by the GLPS regulations.

Explaining the differing treatment of Bio-Tek and Microbac, Complainant points out that as a laboratory, Microbac is an "other person" not included in paragraph (1) within the meaning of FIFRA § 14(a)(2), and thus could only be assessed a penalty subsequent to receipt of a warning letter. Microbac was issued such a letter on June 25, 1992, which lists the violations of GLPS during the two studies performed for Bio-Tek at issue herein (C's Exh 9). Bio-Tek, by contrast, is a registrant within FIFRA § 14(a)(1) and thus is not subject to a similar limitation.

Complainant says that Bio-Tek could easily and should have exercised some minimal [but unspecified] level of control over Microbac's knowledge of, and compliance with, GLPS (Opposition at 5). Complainant alleges that other firms involved with EPA in the settlement of FIFRA, TSCA and EPCRA cases are choosing to develop formalized company-wide procedures which increase the likelihood

that these statutes and applicable regulations will be fully complied with by all employees.

Responding to Bio-Tek's contention that the Agency's failure to provide any directives or guidance on a registrant's duty to investigate or monitor test laboratory compliance with GLP precludes the imposition of a penalty, Complainant alleges that Bio-Tek signed compliance statements that the studies were conducted in accordance with 40 CFR Part 160. Complainant reiterates its contention that Bio-Tek was obligated to take some [undescribed] minimal affirmative steps to ascertain Microbac's knowledge of and compliance with GLPS and alleges that Bio-Tek blindly signed the compliance statement without making any inquiry of Microbac (Opposition at 6).

Complainant acknowledges that the [undescribed] minimal efforts which Bio-Tek allegedly should have taken to ascertain Microbac's GLP compliance would not have obviated all violations, but argues that Bio-Tek should not be able to avoid its responsibility by failing to exercise ordinary caution in selecting a laboratory (Opposition at 7). According to Complainant, a contrary rule would encourage registrants to seek out "questionable" laboratories which would provide the least expensive services by failing to comply with GLP.

Complainant asserts that the Agency is not obligated to codify common sense methods regarding the contractor/contractee relationship, that development of a work plan for the successful completion of a contract is the responsibility of the contracting

parties and that EPA would be unduly interfering in such relationships by the issuance of regulatory directives. Moreover, Complainant contends that Bio-Tek had "fair warning" [notice] of the importance of GLPS regulations, because it was required to submit a compliance statement and the GLPS regulations set forth clear, concise methods for ensuring compliance (Opposition at 8).

Without addressing the precise language of the compliance statements submitted by Bio-Tek, Complainant says that Bio-Tek clearly submitted compliance statements which complied with one of the three options permitted by section 160.12 and contends that, because Bio-Tek made a "direct certification," the statements were not derivative (Opposition at 9). Additionally, Complainant argues that acceptance of the compliance statements is separate from the question of whether the studies were performed in accordance with GLPS and that by accepting the statements, the Agency was not indicating the studies complied with such standards.

Addressing Bio-Tek's contention that there were only two studies and consequently, only two violations, Complainant argues that this "one compliance statement, one violation" theory would have dire consequences on the GLPS program and ultimately on the registration of pesticides (Opposition at 10, 11). This assertedly is due to the fact that the maximum penalty that can be assessed for a single violation is \$5,000, leaving no incentive for the laboratory to prevent additional violations after discovery of the first violation.

D I S C U S S I O N

For the reasons hereinafter appearing, it is concluded that Bio-Tek's motion to dismiss will be denied. Bio-Tek's contention that, because there are only two studies and two compliance statements, only two violations may be charged must, and will, however, be sustained.

Complainant's pre-hearing exchange includes a copy of a report of inspection of Microbac conducted during the period June 25-27, 1991 (C's Exh 1), which contains a copy of statement, purportedly signed by Mr. Carl R. Pampel, laboratory director (C's Exh 2), that various requirements of 40 CFR Part 160, e.g., for a Quality Assurance Unit, were not met. Accordingly, there does not appear to be any dispute, but that GLPS were not complied with in the studies at issue. Curiously, Complainant, while repeatedly alleging that the compliance statement submitted by Bio-Tek was false, makes no attempt to analyze the statement actually submitted and only once obliquely refers to it as representation. As Bio-Tek points out, however, the statements it submitted were literally accurate: "(a) statement attesting to compliance with Good Laboratory Practice Standards, signed by the Study Director, is found above."

If the quoted statement is false in any respect due to the fact the studies referred to were not in fact conducted in accordance with GLPS, it can only be because Bio-Tek's submission of the studies constituted representations the studies were conducted in conformance with GLPS. Bio-Tek, of course, expected

the studies would be acted upon, as apparently occurred, by the granting of its application for registration.

A contrary rule, that Bio-Tek could submit compliance statements such as are at issue here without assuming responsibility for the accuracy of statements by the study director as to compliance with GLPS, would not be an unalloyed benefit to applicants such as Bio-Tek, because it could have the effect of delaying registrations by making the Agency less likely to accept such studies and might ultimately result in registrations for products requiring GLPS being restricted to firms having their own laboratory facilities. Be that as it may, 40 CFR § 160.12(c) appears to provide an "out" by allowing the submission of a study accompanied by a statement that the submitter does not know whether the study was conducted in accordance with GLPS.<sup>4/</sup> Of course, an applicant for registration submitting a study accompanied by such a statement would face the risk that the application would either be rejected outright or, at the very minimum, delayed while EPA investigated whether the study was conducted in accordance with

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<sup>4/</sup> It is recognized that, as written, the option of submitting a statement that the submitter does not know whether the study was conducted in accordance with GLPS is qualified by the requirement that the submitter is not the sponsor of the study and did not conduct the study. The phrase "of one of the following types [of statements]" in section 160.12 appears to allow some flexibility in the language of the statement. In any event, it is noted that the preamble to this portion of the regulation, 48 Fed. Reg. 53948 (November 29, 1983), states in part: "EPA also has decided to allow the applicant the option of stating that he did not conduct or sponsor the study and does not know whether it conforms to GLPs." (emphasis added). It is submitted that the disjunctive "or" between "conduct" "sponsor" is more in keeping with the intent of this provision than the conjunctive "and."

GLPS. While neither the regulation nor the preamble state precisely what action will be taken on such applications,<sup>5/</sup> knowledge of such a result flows directly from the scope of 40 CFR Part 160, i.e., section 160.1 providing in part: "(t)his part prescribes good laboratory practices for conducting studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by the EPA." See also 40 CFR § 160.12 (supra note 2), which emphasizes the importance of compliance statements by the language "a true and correct statement, signed by the applicant, the sponsor and the study director. . . ." and section 160.17(a) "EPA may refuse to consider reliable . . . any data from a study which was not conducted in accordance with this part." Accordingly, it is reasonable to regard a compliance statement, such as that submitted by Bio-Tek herein, as a representation that the referenced study was conducted in accordance with GLPS and to hold the signer responsible, if the statement is false.

Complainant has denied Bio-Tek's assertion that compliance statements similar to those submitted by Bio-Tek herein have been routinely accepted by the Agency in connection with the

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<sup>5/</sup> The preamble to the proposed rules, 48 Fed. Reg. 48928 (December 28, 1987) states in pertinent part: ". . . EPA will decide on a case-by-case basis whether studies which deviate from GLPs are acceptable to support the pesticide product registration or other marketing or research permit."

registration and re-registration of other products.<sup>6/</sup> It is not clear whether this denial extends to Bio-Tek's allegation that, at EPA-sponsored workshops, the Agency has sanctioned the use of sponsor compliance statements such as those submitted by Bio-Tek herein. In any event, if, as we have found, it is reasonable to regard the compliance statements submitted by Bio-Tek as representations that the studies were conducted in accordance with GLPS, Bio-Tek's lack of fair notice and violation of due process arguments disappear, because Bio-Tek can hardly complain if representations it made, when challenged, turn out to be false. Bio-Tek's expectation that the studies it submitted would be relied upon by the granting of its application were apparently realized and Bio-Tek is presumed to be aware of the options provided by section 160.12, i.e., submitting statements describing the differences between the manner of conducting the studies and GLPS or submitting statements that it did not know whether the studies were conducted in accordance with GLPS. Moreover, acceptance of applications for registration of pesticides is separate from the question of whether representations in the application are accurate. Acceptance of an application and issuance of a registration should not and cannot preclude an enforcement proceeding for false statements.

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<sup>6/</sup> Pre-hearing Exchange at 18. By letter, dated March 15, 1993, counsel for Bio-Tek requested that Complainant provide copies of compliance statements submitted since the effective date of GLPS using, inter alia, language similar or equivalent to that submitted by Bio-Tek herein.

Multiple Counts

The complaint in this case is based on FIFRA § 12(a)(2), which provides that "(2) (i)t shall be unlawful for any person to . . . (Q) falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this subchapter; . . . ."

Section 12(a)(2)(Q) was added to the Act by the FIFRA Amendments of 1988, P.L. 100-532 (1988). Legislative history, House Report No. 100-939 (September 20, 1988) "Short Explanation," at 26, Reprinted U.S. Code Congressional and Administrative News (1988), at 3475 describes provisions of the amendments in pertinent part as follows: "Unlawful acts--provides that certain acts (such as submitting false test data, violating suspension or cancellation orders, failure to submit required records or allow inspection) will be unlawful." In other respects, the Report merely repeats the language of the amendment and provides no explanation or rationale for the language used (House Report 100-939, at 63; U.S. Code Cong. & Adm. News, supra at 3512).

Because there were only two identified studies and two separate statements (representations) signed by Bio-Tek that the studies were conducted in accordance with GLPS, presumptively only

two violations of FIFRA § 12(a)(2)(Q) may be charged. There is no indication that Congress in enacting section 2(a)(2)(Q) intended to impose multiple penalties, because "all or part of any information relating to the testing of any pesticide" was false in more than one aspect. Accordingly, there is no more reason to conclude that more than one penalty may be imposed because the studies at issue were not conducted in accordance with GLPS in more than one respect, and thus Bio-Tek's representations were false for more than one reason, than there is for concluding that multiple penalties may be imposed for a single shipment of a pesticide, misbranded in several respects, because the Act specifies that misbranding can occur in multiple ways. Hawk Industries, Inc., supra.<sup>17</sup>

Once it is concluded that the Act does not clearly specify whether multiple penalties may be imposed for the submission of information concerning the testing of any pesticide which is false in more than one respect, well established principles which resolve ambiguities in favor of lenity come into play. Heflin v. United States, 358 U.S. 415 (1959). See also Bell v. United States, 349 U.S. 81, 85 (1955) (Mann Act prosecution involving transportation of more than one woman across state lines on a single trip constituted a single offense for which only one sentence could be

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<sup>17</sup> The rationale of Hawk Industries has been accepted as Agency policy (Enforcement Response Policy For The Federal Insecticide, Fungicide and Rodenticide Act (July 2, 1990) at 26).

imposed, because doubt will be resolved against turning a single transaction into multiple offenses).

The principle that ambiguity is to be resolved in favor of lenity is combined with the test set forth in Blockburger v. United States, 284 U.S. 299 (1932), i.e., whether each count requires proof of a fact the other does not, in determining whether multiple counts are appropriate. See, e.g., United States v. Kennedy, 746 F.2d 546 (9th Cir. 1984), cert. den., 469 U.S. 965 (1984) (in a prosecution under 18 U.S.C. § 1014 for falsifying loan or credit applications, separate sentences may be imposed for each false document or set of false documents submitted); United States v. Sahley, 526 F.2d 913 (5th Cir. 1976) (only one sentence could be imposed for loan document involving a single loan, which contained three false statements). See also United States v. Segall, 833 F.2d 144 (9th Cir. 1987) (defendant properly convicted of three separate offenses (lies) under 18 U.S.C. § 1001 involving receipt of Customs refund checks, because proof of each count involved proof of a fact the other counts did not).

The 1974 Guidelines for the Assessment [of Civil Penalties] Under FIFRA § 14(a)<sup>8/</sup> and the Enforcement Response Policy For

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<sup>8/</sup> The 1974 Guidelines, 39 Fed. Reg. 27711 (July 31, 1974), provide at § B(2):

(2) What constitutes an independently assessable charge. A separate civil penalty shall be assessed for each violation of the Act which results from an independent act (or failure to act) of the respondent and which is substantially distinguishable from any other charge in the complaint for which a civil penalty is to be assessed. In determining whether a given charge is  
(continued...)

FIFRA (July 2, 1990)<sup>2/</sup> in effect incorporate the Blockburger test by specifying that a separate penalty shall be assessed for each independent act or failure to act which is substantially distinguishable from any other charge for which a penalty is to be assessed in the complaint. In contrast, the Enforcement Response Policy For The FIFRA GLP Regulations (September 30, 1991) departs

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<sup>8/</sup>(...continued)

independent of and substantially distinguishable from any other charge for purposes of assessing separate penalties, complainant must consider whether each provision requires an element of proof not required by the other. Thus, not every charge which may appear in the complaint shall be separately assessed. Where a charge derives primarily from another charge cited in the complaint for which a penalty is proposed to be assessed, the subsequent charge may not warrant a separate assessment. The complaint will propose to assess an appropriate civil penalty for each independent and substantially distinguishable charge.

<sup>2/</sup> The 1990 FIFRA Enforcement Response Policy provides at 25 "Independently Assessable Charges:

A separate civil penalty, up to the statutory maximum, shall be assessed for each independent violation of the Act. A violation is independent if it results from an act (or failure to act) which is not the result of any other charge for which a civil penalty is to be assessed, or if the elements of proof for the violations are different. Dependent violations may be listed in the complaint, but will not result in separate civil penalties.

Consistent with the above criteria, the Agency considers violations that occur from each shipment of a product (by product registration number, not individual containers), or each sale of a product, or each individual application of a product to be independent offenses of FIFRA.\* Each of these independent violations of FIFRA are subject to civil penalties up to the statutory maximum of \$5,000 for section 14(a)(1) and \$1,000 for section 14(a)(2). . . .

from these well established principles and provides that each independent requirement of GLPS which has been violated may be considered a separate count and a separate penalty assessed therefor up to the statutory maximum, notwithstanding there is only one compliance statement.<sup>10/</sup> In this regard, Complainant argues that requiring a [separate] compliance statement for each provision of the GLP regulation would be a needless waste of time and paper (Opposition at 10). This argument would have some force, if the FIFRA Enforcement Response Policy for GLP regulations had been promulgated in accordance with notice and comment rulemaking requirements of the Administrative Procedure Act so that the public could be said to be on notice thereof.

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<sup>10/</sup> The 1991 FIFRA Enforcement Policy provides in pertinent part at 7 "Multiple Violations:"

A statement, under 40 CFR 160.12, which certifies that a study complies with the GLPs is a statement that all requirements listed in 40 CFR Part 160 have been met. If requirements of the GLPs have not been met, then the GLP compliance statement is false. Each independent requirement of the GLPs which has been violated, but has been represented through the statement as in compliance, may be considered a separate count of FIFRA section 12(a)(2)(M) or 12(a)(2)(Q), as appropriate, and each count assessed a civil penalty up to the statutory maximum (see the July 2, 1990 FIFRA ERP, page 25, for a discussion of independently assessable charges). For example, a sponsor could be assessed a civil penalty for up to \$15,000 because that sponsor submitted a study with a GLP compliance statement which failed to truthfully state that the pesticide testing facility: (1) failed to maintain personnel records; (2) failed to designate a study director; and (3) failed to record raw data.

\* \* \* \*.

The essence of the violation here, no less than the essence of the violations in the cited cases involving prosecutions under 18 U.S.C. §§ 1001 and 1014, is the submission of false statements and, absent some indication such a result was contemplated by Congress or, at the very least, a published regulation, a single statement or piece of information, which is false in more than one respect, submitted to the Agency in connection with a single transaction such as the studies at issue here, may not be turned into multiple violations for which multiple penalties may be assessed. The 1991 GLP Enforcement Response Policy is contrary to the precedent cited above, contrary to the Agency's 1990 FIFRA Enforcement Response Policy, is not in accordance with the law and is simply arbitrary.<sup>11/</sup> It is concluded that, because there were only two studies and two compliance statements, only two penalties may be assessed.<sup>12/</sup>

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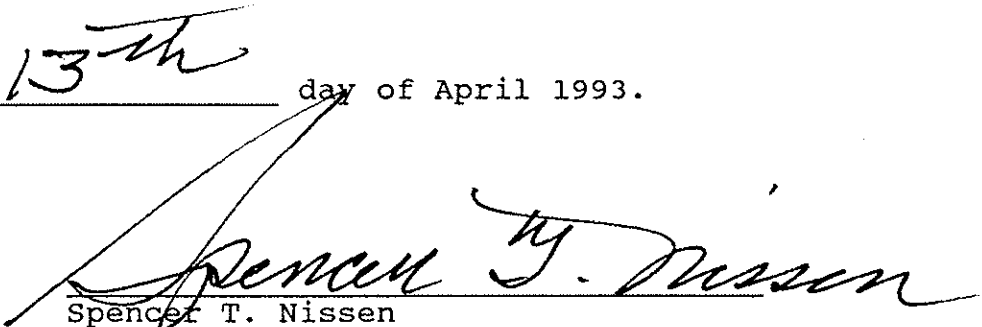
<sup>11/</sup> In a letter to the ALJ, dated March 29, 1993, counsel for Bio-Tek points out that the Agency treated the violations by the laboratory, Microbac, as a single violation, but nevertheless, attempts to assess Bio-Tek penalties for 23 violations involving the same studies.

<sup>12/</sup> Complainant's assertion that the "one compliance statement one violation" theory is analogous to charging a motorist one count for multiple speeding violations is inapt and misplaced, because whether more than one count is proper obviously depends on the time and place of the speeding infractions. A more appropriate analogy is a defendant who drives recklessly, endangering life, limb or property, by speeding, running a stoplight and going the wrong way on a one-way street. Assuming these traffic violations occurred on one continuous trip or excursion, only one count of reckless driving would be proper even though the reckless driving was committed by multiple acts.

O R D E R

Bio-Tek's motion to dismiss is denied. Bio-Tek's contention that, because there were only two studies and only two compliance statements, only two counts of false statements may be charged is sustained.

Dated this 13<sup>th</sup> day of April 1993.

  
Spencer T. Nissen  
Administrative Law Judge

CERTIFICATE OF SERVICE

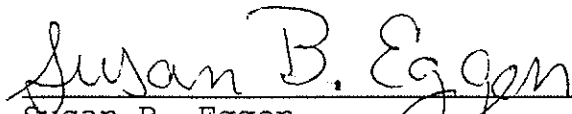
I do hereby certify that the foregoing Order Denying Motion to Dismiss Based On Threshold Legal Issues was filed in re Bio-Tek Industries, Inc.; Docket No. FIFRA-92-H-06 and a copy of the same was mailed to the following:

(Inter Office)

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Dated: April 13, 1993